

Claims

1. Osteoconductive/ osteoinductive titanium/titanium alloy implant comprising an additional element in the titanium oxide, obtained by anodic oxidation,
5 **characterised in,**
that said additional element is chosen from the group consisting of calcium, phosphor or sulphur and that said implant exhibits a cross-section of the osteoconductive/ osteoinductive oxide layer, which consists of a double layer structure of an upper porous layer and a lower compact barrier layer.
- 10 2. Implant according to claim 1, wherein the porous upper layer exhibits an open structure comprising a plurality of shallow craters.
3. Implant according to claim 1 or 2, wherein the upper layer has a thickness below about
15 1000 nm, preferably 100–500 nm.
4. Implant according to any of the preceding claims to, wherein the lower barrier layer has a thickness ranging between about 300 nm and 2000 nm, preferably 600-1500 nm.
- 20 5. Implant according to any of the preceding claims, wherein the thickness of said osteoconductive/osteoinductive double layer-structured oxide containing an additional element is from 300 to 3000 nm, preferably between 800 and 1500 nm.
6. Implant according to any of the preceding claims, wherein the lower barrier layer
25 comprises less of said additional element than the upper porous layer.
7. Implant according to any of the preceding claims, wherein the lower barrier layer does not include any pores/craters or channels.
- 30 8. Implant according to any of the preceding claims, wherein the upper porous layer exhibits more than about 11 % porosity and less than about 30 %, preferably about 15 %.
9. Implant according to any of the preceding claims, wherein the crystal structure of titanium oxide is amorphous and/or amorphous and anatase and/or amorphous, anatase and rutile.

10. Implant according to any of the preceding claims, wherein the relative concentration of the additional element incorporated into the anodic oxide layer formed on titanium/titanium alloy implants increases with the thickness of the oxide layer containing an additional element.

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11. Implant according to any of the preceding claims, wherein the relative concentration of the additional element in of the oxide layer of said implant is between 1 % and 50 %, preferably between 1 % and 25 %.

10 12. A process of producing a osteoconductive/osteoinductive titanium/titanium alloy implant comprising an additional compound as a titanium oxide component, wherein the additional compound is chosen from the group consisting of calcium, phosphor or sulphur, using a electrochemical oxidation method, comprising the steps of:

- 15 c) providing anodic electrochemical oxidation of the titanium/titanium alloy implant in an electrolyte containing at least one of said additional components,
- d) controlling the anodic forming voltage transient with slope (dV/dt), as to produce an oxide layer on said titanium/titanium alloy implant exhibiting a double layer structure of an upper porous layer and a lower compact barrier layer.

20 13. A process according to claim 12, further comprising the steps of controlling the anodic forming voltage transient with slope (dV/dt) and interrupting the oxidation process when dV/dt is between 0.2-0.4, preferably about 0.3.

25 14. A process of producing osteoconductive/osteoinductive titanium/titanium alloy implants comprising an additional compound as a titanium oxide component, wherein the additional compound is chosen from the group consisting of calcium, phosphor or sulphur, using a electrochemical oxidation method, micro arcing oxidation, comprising the steps of:

- 30 a) controlling the anodic forming voltage transient with slope (dV/dt), oxide growth constant (α , nm/V), the current efficiency (nm.cm²/C), the anodic oxide forming rate (nm/sec);
- b) controlling the intensity and extent of breakdown phenomenon and breakdown voltage;
- c) controlling the incorporation of either calcium, phosphorous or sulphur into the double layer structure of a upper porous and a lower barrier oxide layer by colloidal deposition mechanism,

- d) controlling reinforcement of the mechanical properties of said calcium-containing oxide for long term functional loading in the human body - to strictly confine the anodising time from the first onset of micro arcing phenomenon on the titanium/titanium alloy anode to near anodic forming voltage transient with slope $dV/dt \approx 0.3$, during the different phases of the anodic process;
- e) detecting the first onset of said micro arcing phenomenon of said process during the oxidation;
- f) maintaining said process by near anodic forming voltage transient with the slope, dV/dt being about 0.3.

15. Process according any of the claims 12-14, wherein current density (mA/cm^2) ranges from 30 to $4000 \text{ mA}/\text{cm}^2$, preferably from 60 to $2000 \text{ mA}/\text{cm}^2$.

16. Process according to any of the claims 12-15, wherein the anodic forming voltage ranges from 30 to 500 V, preferably from 250 to 500 V.

17. Process according to any of the claims 12-16, wherein the temperature during the process ranges from 10 to 100°C , preferably from 10 to 50°C .

18. A process of producing a osteoconductive/osteoinductive titanium/titanium alloy implant comprising calcium as a titanium oxide component, wherein said titanium /titanium alloy implant is electrochemically anodically oxidised in (a) at least one calcium-containing electrolyte and (b) ethylene diamine tetra acetic acid to yield a calcium-containing implant.

19. Process according to claim 18, wherein the calcium-containing electrolyte used in the anodising process is chosen from the group consisting of: calcium acetate, calcium carbonate, calcium chloride, calcium citrate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium nitrate, and calcium sulphate.

20. Process according to any of the claims 18-19, wherein the anodic oxidation is performed at an alkaline pH value.

21. Process according to any of the claims 18-20, wherein mixture used in the anodic oxidation process also includes weak acid electrolytes, chosen from the group consisting of

boric acid, maleic acid, malonic acid, oxalic acid and succinic acid.

22. Process according to any of the claims 18-21, wherein mixture used in the anodic oxidation process also includes a phosphor-containing compound.

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23. Calcium-containing titanium/titanium alloy implant obtained by the process according to any of the claims 12-22.

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24. A process of producing osteoconductive/osteoinductive titanium/titanium alloy implants comprising phosphor as a titanium oxide component, wherein said titanium/titanium alloy implant is electrochemically anodically oxidised in at least one phosphor-containing electrolyte to yield a phosphor-containing implant.

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25. Process according to claim 24, wherein the phosphor-containing electrolyte used in the anodising process is chosen from the group consisting of: phosphoric acid, glycerol-phosphate, sodium phosphate, sodium pyrophosphate, sodium phosphinate, ammonium phosphate, potassium phosphate.

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26. Phosphor-containing titanium/titanium alloy implant obtained by the process according to any of the claims 12-17 or 24-25.

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27. A process of producing osteoconductive/osteoinductive titanium/titanium alloy implants comprising sulphur as a titanium oxide component, wherein said titanium/titanium alloy implant is electrochemically anodically oxidised in at least one sulphur-containing electrolyte to yield a sulphur-containing implant.

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28. Process according to claim 27, wherein the sulphur-containing used in the anodising process is chosen from the group consisting of: sulphuric acid, potassium sulphate, sodium sulphate, sodium thiosulphate, sodium hydrosulphite and sodium pyrosulphite.

29. Sulphur-containing titanium/titanium alloy implant obtained by the process according to any of the claims 12-17 or 27-28.

30. Titanium/titanium alloy implant comprising an additional element in the titanium oxide, obtained by anodic oxidation, wherein said additional element is chosen from the group consisting of calcium, phosphor or sulphur and that said implant exhibits a cross-section of the oxide layer, comprising an upper porous layer and a lower compact barrier layer.

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